

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of claims:

Claim 56 (original): A compressed pharmaceutical tablet or a direct compressed pharmaceutical tablet, wherein the dispersion contains particles comprising a DPP-IV inhibitor which is (S)-1-[(3-hydroxy-1-adamantyl)amino]acetyl-2-cyano-pyrrolidine in free form or in acid addition salt form, and wherein at least 60% of the particle size distribution in the tablet is less than 250 μm .

Claim 57 (currently amended): A compressed pharmaceutical tablet or a direct compressed pharmaceutical tablet according to claim 56, wherein the dispersion contains particles comprising DPP-IV inhibitor which is (S)-1-[(3-hydroxy-1-adamantyl)amino]acetyl-2-cyano-pyrrolidine in free form or in acid addition salt form, and wherein;

- i) at least 60% of the particle size distribution in the tablet is ~~less than 250 μm~~ preferably between 10 to 250 μm , and
- ii) tablet thickness to tablet weight ratios is of 0.002 to 0.06 mm/mg or of 0.01 to 0.03 mm/mg

Claim 58 (currently amended): A compressed pharmaceutical tablet or a direct compressed pharmaceutical tablet according to claim 56, wherein the dispersion contains particles comprising DPP-IV inhibitor which is (S)-1-[(3-hydroxy-1-adamantyl)amino]acetyl-2-cyano-pyrrolidine in free form or in acid addition salt form, and wherein;

- i) at least 60% of the particle size distribution in the tablet is ~~less than 250 μm~~ preferably between 10 to 250 μm ,
- ii) the water content of the tablet is less than 10% after 1 week at 25°C and 60% RH, and
- iii) tablet thickness to tablet weight ratios is of 0.002 to 0.06 mm/mg.

Claim 59 (original): A compressed pharmaceutical tablet or a direct compressed pharmaceutical tablet according to claim 56, wherein the particle size distribution in the tablet is between 50 to 150 μm .

Claim 60 (original): A compressed pharmaceutical tablet or a direct compressed pharmaceutical tablet according to claim 56, wherein the water content of the tablet is less than 5% after 1 week at 25°C and 60% RH

Claim 61 (original): A compressed pharmaceutical tablet or a direct compressed pharmaceutical tablet according to claim 56, wherein tablet thickness to tablet weight ratios is of 0.01 to 0.03 mm/mg

Claim 62 (original): A compressed pharmaceutical tablet or a direct compressed pharmaceutical tablet according to claim 56, wherein at least 60% or at least 80% of the particle size distribution in the tablet is between 10 to 250 μm .

Claim 63 (original): A compressed pharmaceutical tablet or a direct compressed pharmaceutical tablet according to claim 56, wherein at least 25% or at least 35% of the particle size distribution in the tablet is between 50 to 150 μm .

Claim 64 (original): A compressed pharmaceutical tablet or a direct compressed pharmaceutical tablet according to claim 56, wherein the tablet comprises

- (a) 5-60% by weight on a dry weight basis of a DPP-IV inhibitor which is (S)-1-[(3-hydroxy-1-adamantyl)amino]acetyl-2-cyano-pyrrolidine in free form or in acid addition salt form;
- (b) 40-95% by weight on a dry weight basis of a pharmaceutically acceptable diluent;
- (c) 0-20% by weight on a dry weight basis of a pharmaceutically acceptable disintegrant; and optionally
- (d) 0.1-10% by weight on a dry weight basis of a pharmaceutically acceptable lubricant.

Claim 65 (currently amended): A compressed pharmaceutical tablet or a direct compressed pharmaceutical tablet according to claim 56, wherein the tablet comprises

- (a) 20-40% preferably ~~20-35%~~ by weight on a dry weight basis of a DPP-IV inhibitor which is (S)-1-[(3-hydroxy-1-adamantyl)amino]acetyl-2-cyano-pyrrolidine in free form or in acid addition salt form;
- (b) 40-95% by weight on a dry weight basis of a pharmaceutically acceptable diluent;
- (c) 0-10% by weight on a dry weight basis of a pharmaceutically acceptable disintegrant; and optionally
- (d) 0.25-6% by weight on a dry weight basis of a pharmaceutically acceptable lubricant.

Claim 66 (original): A compressed pharmaceutical tablet or a direct compressed pharmaceutical tablet according to claim 56, wherein the tablet comprises

- (a) 20-35% by weight on a dry weight basis of a (S)-1-[(3-hydroxy-1-adamantyl)amino]acetyl-2-cyano-pyrrolidine in free form or in acid addition salt form;
- (b) 62-78% by weight on a dry weight basis of a pharmaceutically acceptable diluent;
- (c) 0-10% by weight on a dry weight basis of a pharmaceutically acceptable disintegrant; and optionally
- (d) 0.1-10% by weight on a dry weight basis of a pharmaceutically acceptable lubricant.

Claim 67 (original: A compressed pharmaceutical tablet or a direct compressed pharmaceutical tablet according to claim 56, wherein the tablet comprises;

- (a) 22-28% by weight on a dry weight basis of a (S)-1-[(3-hydroxy-1-adamantyl)amino]acetyl-2-cyano-pyrrolidine in free form or in acid addition salt form.

Claim 68 (original): A compressed pharmaceutical tablet or a direct compressed pharmaceutical tablet according to claim 56, comprising;

- (a) 30-35 % by weight on a dry weight basis of a (S)-1-[(3-hydroxy-1-adamantyl)amino]acetyl-2-cyano-pyrrolidine in free form or in acid addition salt form, and

(b) 58-72% by weight on a dry weight basis of a pharmaceutically acceptable diluent;

Claim 69 (currently amended): A compressed pharmaceutical tablet or a direct compressed pharmaceutical tablet according to claim 56, comprising;

- i) one or two diluents selected from microcrystalline cellulose and lactose
- ii) the two diluents microcrystalline cellulose and lactose,
- iii) 25-70% ~~preferably 35-55%~~ by weight on a dry weight basis of a pharmaceutically acceptable microcrystalline cellulose, or
- iv) 25-70% ~~preferably 35-55%~~ by weight on a dry weight basis of a pharmaceutically acceptable microcrystalline cellulose and 5-40% ~~preferably 18-35%~~ by weight on a dry weight basis of lactose.

Claim 70 (original): A compressed pharmaceutical tablet or a direct compressed pharmaceutical tablet according to claim 56 comprising;

- (c) 1-6% by weight on a dry weight basis of a pharmaceutically acceptable disintegrant, and/or
- (d) 0.1-10% by weight on a dry weight basis of a pharmaceutically acceptable lubricant.;

Claim 71 (original): A compressed pharmaceutical tablet or a direct compressed pharmaceutical tablet according to claim 56 comprising;

- (a) 20-35% by weight on a dry weight basis of (S)-1-[(3-hydroxy-1-adamantyl)amino]acetyl-2-cyano-pyrrolidine in free form or in acid addition salt form;
- (b) 25-70% by weight on a dry weight basis of a pharmaceutically acceptable microcrystalline cellulose;
- (c) 5-40% by weight on a dry weight basis of a pharmaceutically acceptable lactose;
- (d) 0-10% by weight on a dry weight basis of a pharmaceutically acceptable sodium starch glycolate;
- (e) 0.25-6% by weight on a dry weight basis of magnesium stearate.

Claim 72 (currently amended): A compressed pharmaceutical tablet or a direct compressed pharmaceutical tablet according to claim 56 comprising;

- (a) 30-35% ~~preferably 30-32%~~ by weight on a dry weight basis of (S)-1-[(3-hydroxy-1-adamantyl)amino]acetyl-2-cyano-pyrrolidine in free form or in acid addition salt form;
- (b) 35-50% ~~preferably 40-45%~~ by weight on a dry weight basis of a pharmaceutically acceptable microcrystalline cellulose;
- (c) 18-35% ~~preferably 20-25%~~ by weight on a dry weight basis of a pharmaceutically acceptable lactose;
- (d) 1-4% ~~preferably 1.5-2.5%~~ by weight on a dry weight basis of a pharmaceutically acceptable sodium starch glycolate; and
- (e) 0.5-4% ~~preferably 0.1-2%~~ by weight on a dry weight basis of magnesium stearate.

Claim 73 (currently amended): A compressed pharmaceutical tablet or a direct compressed pharmaceutical tablet according to claim 56 comprising;

- (a) 20-35% ~~preferably 22-28%~~ by weight on a dry weight basis of of (S)-1-[(3-hydroxy-1-adamantyl)amino]acetyl-2-cyano-pyrrolidine in free form or in acid addition salt form;
- (b) 35-55% by weight on a dry weight basis of a pharmaceutically acceptable microcrystalline cellulose;
- (c) 18-35% by weight on a dry weight basis of a pharmaceutically acceptable lactose;
- (d) 1-4% by weight on a dry weight basis of a pharmaceutically acceptable sodium starch glycolate; and
- (e) 0.5-4% by weight on a dry weight basis of magnesium stearate.

Claim 74 (original): A compressed pharmaceutical tablet or a direct compressed pharmaceutical tablet according to claim 56 comprising;

- (a) from about 22% to about 28% by weight on a dry weight basis of (S)-1-[(3-hydroxy-1-adamantyl)amino]acetyl-2-cyano-pyrrolidine in free form or in acid addition salt form;
- (b) from about 45% to about 50% by weight on a dry weight basis of a pharmaceutically acceptable microcrystalline cellulose;

- (c) from about 20% to about 25% by weight on a dry weight basis of a pharmaceutically acceptable lactose;
- (d) from about 1.5% to about 2.5% by weight on a dry weight basis of a pharmaceutically acceptable sodium starch glycolate; and
- (e) from about 0.1% to about 2% by weight on a dry weight basis of magnesium stearate.

Claim 75 (original): A compressed pharmaceutical tablet or a direct compressed pharmaceutical tablet according to claim 56, wherein

- i) between 0 and 10 minutes 85 to 99.5 % of the active ingredient is released, and
- ii) between 10 and 15 minutes 90 to 99.5 % of the active ingredient is released.

Claim 76 (original): A compressed pharmaceutical tablet or a direct compressed pharmaceutical tablet according to claim 56, wherein the particle size distribution of the pharmaceutical excipients in the tablet is between 5 and 400 μm .

Claim 77 (original): A compressed pharmaceutical tablet according to claim 56, which is a direct compressed tablet.

Claim 78 (original): Process for preparing a direct compressed tablet in unit dosage form, which comprises:

(a) blending as a % by weight on a dry weight basis:

- (i) 6-60% by weight on a dry weight basis of DPP-IV inhibitor; and
- (ii) and at least one excipient selected from a diluent, a disintegrant and a lubricant,

to form a DPP-IV inhibitor formulation in the form of a tableting powder, capable of being directly compressed into a tablet; and

(b) compressing the formulation prepared during step (a) to form the compressed DPP-IV inhibitor tablet in unit dosage form

said DPP-IV inhibitor being (S)-1-[(3-hydroxy-1-adamantyl)amino]acetyl-2-cyanopyrrolidine in free form or in acid addition salt form.

Claim 79 (original): Process for preparing a direct compressed tablet according to claim 78, in unit dosage form, which comprises:

(a) blending as a % by weight on a dry weight basis:

- (i) 25-35% by weight on a dry weight basis of DPP-IV inhibitor;
- (ii) 40-95% by weight on a dry weight basis of a pharmaceutically acceptable diluent;
- (iii) 0-10% by weight on a dry weight basis of a pharmaceutically acceptable disintegrant; and
- (iv) 0.25-6% by weight on a dry weight basis of a pharmaceutically acceptable lubricant,

to form a DPP-IV inhibitor formulation in the form of a tableting powder, capable of being directly compressed into a tablet; and

- (b) compressing the formulation prepared during step (a) to form the compressed DPP-IV inhibitor tablet in unit dosage form, said DPP-IV inhibitor being (S)-1-[(3-hydroxy-1-adamantyl)amino]acetyl-2-cyano-pyrrolidine in free form or in acid addition salt form.

Claim 80 (currently amended): Process according to claim 78 wherein the blended formulation comprises:

- (i) 20-35% or preferably 25-30% by weight by weight on a dry weight basis of (S)-1-[(3-hydroxy-1-adamantyl)amino]acetyl-2-cyano-pyrrolidine in free form or in acid addition salt form, in free form or in acid addition salt form;
- (ii) 25-70% by weight or preferably 35-50% by weight on a dry weight basis of a pharmaceutically acceptable microcrystalline cellulose such as Avicel PH 102;
- (iii) 5-40% by weight or preferably 18-35% by weight on a dry weight basis of a pharmaceutically acceptable lactose;
- (iv) 0-10% by weight or preferably 1-4% by weight on a dry weight basis of a pharmaceutically acceptable sodium starch glycolate; and
- (v) 0.25- 6% by weight or preferably 0.5-4% by weight on a dry weight basis of a pharmaceutically acceptable magnesium stearate.